

I. The Office Action

The June 13, 2008 Office Action (the "Office Action") in this application:

- 1.) rejects claims 11 and 34-44 under 35 U.S.C. 103(a); and
- 2.) twice provisionally rejects claims 11 and 34-44 on the ground of nonstatutory obviousness-type double patenting.

Applicants respond as follows.

II. Remarks: Amended claim 11

Claim 11 is hereby amended to recite and limit the secretion recited in this claim to, specifically, secretion from atypical tissue of the mammary gland, thus specifying the origin of the secretion. Thus, and as one of ordinary skill in the art will easily and clearly understand from a complete reading of the specification, this secretion is limited to atypical tissue, and in particular, atypical tissue of the mammary gland (i.e. non-typical tissue, e.g. hyperplastic or hypertonic), support for which may be found at least in original claim 15 and paragraph [0104] of the published specification). Thus claim 11 positively recites and is specified to be applicable specifically to atypical tissue of the mammary gland.

III. Rejection of claims 11 and 34-44 under 35 U.S.C. 103(a):

The Office Action rejects claims 11 and 34-44 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2001/0043930 A1 and in further view of Wald and Klaus (The Australian and New Zealand Journal of Surgery 33(3): 200-204, February 1964) and U.S. Patent No. 6,312,708, as evidenced by Vakil et al. (C.M.A Journal 109: 29-32, July 7, 1973). Applicants respectfully traverse this rejection.

The Office Action asserts that "Foremost, Vakil notes and certain axillary sweat glands are histologically of the apocrine type and their secretions are biochemically similar." (see Office Action mailed 6-13-08, page 4, first sentence of the third paragraph). Respectfully, Applicants disagree.

Based on a close reading of Vakil et al., Applicants are at a loss to locate or substantiate any of the Office Action's asserted disclosure of Vakil et al. relating to "axillary sweat glands are histologically of the apocrine type and their secretions are biochemically similar". Vakil et al. simply discusses etiological topics such as the tendency toward cancer found in particular families, brought to light as a result of pedigree studies, effects of inbreeding on the likelihood of breast cancer development, genetic markers, chromosomal anomalies and their role in tumor progression, for example (Etiology of breast cancer I. Genetic aspects (this is the title of the Vakil et al. paper)). There is no disclosure in Vakil as asserted by the Office action, and indeed this reference does not appear to be relevant or related to the instant claims. The Office Action must provide some sort of rational or reasoned articulation as to why one of ordinary skill in the art would look to, and further, even combine this references with the other disparate references cited. Applicants respectfully assert that the Office has not done so.

Accordingly, the Office Action's reliance on this irrelevant reference is improper, as well as its asserted rejection "...as evidenced by Vakil et al.", and accordingly citation of U.S. Patent 6,312,708, (directed to a specific method of botulinum toxin delivery via implant). Neither Vakil et al or U.S. Patent 6,312,708 alone or in any combination with previously cited U.S. Patent Application Publication 2001/0043930 or Wald and Klaus remedy the deficiencies of the combination of U.S. Patent Application Publication 2001/0043930 or Wald and Klaus, as detailed in Applicant's previous reply.

Applicants respectfully maintain their previous arguments made in their replies of Oct. 2, 2007 and March 28, 2008. The inclusion of Vakil et al. and/or U.S. Patent 6,312,708 does not remedy the state of the Office Action's misconstruction of the teachings of the Wald and Klaus document. The Office Action's purview, that the substance of the apocrine glands "is a mucus secretion", which is the basis of the Office Action's combination of the Wald and Klaus and U.S. Patent Application Publication 2001/0043930 references, is still untenable and is not supported by or bolstered by Vakil's discussion regarding familial propensity to develop breast cancer, or the association between "wet" or

“dry” ear wax and rates of breast cancer in diverse population groups, nor by the citation of U.S. Patent Application Publication 2001/0043930 A1, which does not disclose utilizing botulinum toxin to treat mammary gland disorders.

We note again that there is no discussion or hint of botulinum toxin use in Wald and Klaus, and there is no discussion in U.S. Patent Application Publication 2001/0043930 A1 (the primary and secondary references now cited in the 103 (a) rejection) regarding the treatment of mammary gland disorders, particularly cancerous disorders.

The combination of the references appears to still be based upon the Office Action’s initial misconstruction that the secretions of apocrine glands are mucus, instead of the odoriferous secretion (pheromone), as detailed in Wald and Klaus, now expanded improperly include any secretion. The combination of the **four** documents in the current rejection is simply an even more complicated exercise in hindsight reconstruction (recall that U.S. Patent Application Publication 2001/0043930 A1 does not disclose utilizing botulinum toxin to treat mammary gland disorders or pheromones for that matter, and Walk and Klaus are silent as to any treatment of apocrine carcinoma other than surgical excision and X-ray irradiation).

Thus, this rejection should be withdrawn.

VI. Provisional rejection of claims 11 and 34-44 on the grounds of non-statutory obviousness-type double patenting

The Office Action has provisionally rejected claims 11 and 34-44 on the grounds of non-statutory obviousness-type double patenting as being unpatentable over claims 1-13 of co-pending Application No 10/929,404 (filed August 27, 2004) and claims 21-28 and 31 of co-pending Application No 11/192,777 (filed December 11, 2007). Applicants respectfully traverses this rejection because the applications cited by the Office Action were filed after the filing of the instant case, and according to MPEP 804(I)(B.)(1), a provisional obviousness type double patenting rejection should be withdrawn, if that rejection is the only grounds remaining in the earlier filed application (the instant application) and allowed to issue without a terminal disclaimer. Applicant respectfully requests withdrawal of the obviousness type double patenting rejection over the later filed cited co-pending applications, once it is the only remaining grounds of rejection.

VII. Conclusion

All issues raised in the Office Action have been addressed. Only claims 11, 34-44 remain, which are in condition for allowance. Accordingly, a notice of allowance to that effect is respectfully solicited.

Should any matter(s) remain unresolved, the Examiner is invited to call Claude L. Nassif at the number below.

The Commissioner is hereby authorized to charge any fee(s) required or necessary for the filing, processing or entering of this paper or any of the enclosed papers and to refund any overpayment to deposit account 01-0885.

Respectfully submitted,

/CLAUDE L. NASSIF/

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